Alleged Indefiniteness

Claims 1 to 20 and 28 to 43 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants traverse these rejections for the following reasons.

A. The Office Action asserts that claims 1 and 9 are drawn to a method for transforming a plant with a transgene, but no transgene is recited in the steps of the claims. Without conceding the correctness of the assertion, and to advance prosecution by further clarifying the claimed subject matter, claims 1 and 9 have been amended to recite "electroporating the cultured explant ***and at least one transgene***" (emphasis added). Support for the amendment is found in the specification as filed at, for example, the Examples. Applicants respectfully submit that the rejection has been obviated, and request withdrawal thereof.

B. The Office Action asserts that use of the term "intact" in claim 1 to describe an explant is contradictory because an explant is tissue removed from a plant. Without conceding the correctness of the assertion, and to advance prosecution by further clarifying the claimed subject matter, claims 1 and 9 have been amended to delete the word "intact" and to recite that the cells of the explant are not subjected to enzymatic digestion or partial enzymatic digestion of their cell walls. Support for the amendment is found in the specification as filed, at, for example, the last full paragraph of page 7. Applicants accordingly request withdrawal of the rejection.

C. The Office Action asserts that the term "the explant" lacks antecedent basis. Applicants assume that the Office Action is referring to recitation of "the explant" in step (b) of claims 1 and 9. Without conceding the correctness of the assertion, and to advance prosecution by further clarifying the claimed subject matter, claims 1 and 9 have been

amended to recite "the cultured explant," which those skilled in the art would understand to refer to the explant that is cultured in step (a) of each claim. Applicants respectfully submit that the rejection has thus been obviated.

D. The Office Action asserts that claim 1 recites an incomplete method because the final step of the method does not produce "the claimed product." Applicants respectfully submit that a ***product*** is not being claimed in claim 1. Rather, claim 1 recites a ***method*** for transforming a plant with a transgene that ***comprises*** steps (a) and (b). Due to the use of the transitional phrase "comprising," the claim can encompass additional method steps. M.P.E.P. § 2111.03. Accordingly, Applicants respectfully submit that those skilled in the art would readily understand the metes and bounds of claim 1 when the claim is read in light of the specification. The requirements of the second paragraph of § 112 have therefore been fulfilled. *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993) (stating that "if the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 [second paragraph] demands no more.").

E. The Office Action asserts that the terms "gene" and "transgene" are unclear because the term "gene" implies a DNA sequence that exists in nature and includes coding regions, noncoding regions, and regulatory sequences associated with expression. Without conceding the correctness of the assertion, and to advance prosecution by further clarifying the claimed subject matter, claims 7, 8, and 15 to 18 have been amended to replace the term "marker gene" with the phrase "nucleic acid encoding a marker." Claim 18 has been amended to replace the phrase "the marker gene is the IPT gene" with the phrase "the nucleic acid encoding a marker encodes isopentenyl transferase." In addition, with respect to "transgene," the term is defined in the specification consistent with its meaning to those skilled in the art as "a desired DNA to be electroporated into an explant resulting in a

transgenic plant." (See the paragraph spanning pages 9 and 10 of the specification.) Accordingly, Applicants respectfully submit that the term is clear and definite.

F. The Office Action asserts that the term "modifies" in claim 36 is unclear because "what the modification consists of is not described." Office Action dated January 15, 2003, page 4. Without conceding the correctness of the assertion, claim 36 has been cancelled, obviating the rejection.

G. The Office Action asserts that, with respect to claims 35 to 43, reciting the names of specific genes, or a functional or structural feature of a gene, does not define the metes and bounds of the genera encompassed by the claims. Without conceding the correctness of the assertion, and to advance prosecution, claims 35 to 43 have been cancelled, obviating the rejection. Accordingly, Applicants respectfully request withdrawal thereof.

Alleged Lack of Enablement

Claims 1 to 19 and 30 to 43 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. The Office Action asserts that the specification is enabling for a method of transforming a plant with a transgene, comprising (a) culturing an intact explant of chrysanthemum, rosa, or petunia in nutritive medium, (b) electroporating the explant with a pulse length of at least about 50 miliseconds but not more than 800 miliseconds, to produce a transformed explant, wherein the transgene is stably integrated into a chromosome of a cell of the transformed explant, but is not enabling for a method where the transformed plant is a monocot or gymnosperm. Applicants respectfully traverse the rejection because the Office Action has failed to establish that the specification does not enable the claimed subject matter.

When making an enablement rejection, the Examiner bears the initial burden of establishing a reasonable basis to question the enablement provided for the claimed subject matter. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). A specification that contains a teaching of the manner and process of making and using an invention in terms that correspond in scope to those used in describing and defining the subject matter sought to be patented ***must be taken as being in compliance with the enablement requirement*** unless there is a reason to doubt the objective truth of the statements contained therein. M.P.E.P. §2164.04. "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971).

The Office Action has failed to establish that those of skill in the art, upon review of the specification, would be unable to practice the claimed subject matter without undue experimentation. The specification provides abundant guidance to those skilled in the art regarding the culture media and culture conditions that can be used to culture explants of plants that are to be transformed. (See pages 8 to 9 of the specification as filed.) In addition, the specification teaches those of skill in the art the appropriate conditions for electroporation of the cultured explants and at least one transgene, including the time and voltage of the pulse. (See pages 11 to 12 of the specification as filed.) The specification further describes procedures that can be undertaken after electroporation that allow the plant tissue to recover, and teaches that "[t]he method of the invention is applicable to any plant for which a tissue culture system is available or can be developed." (See the last paragraph of page 12 of the specification as filed and the second full paragraph of page 7 of the specification as filed.)

Accordingly, there is no reason to believe that those of skill in the art would be unable to practice the full scope of the subject matter defined by the claims.

Although the Office Action alleges that "[i]t is unpredictable that systems developed for dicots, petunias and chrysanthemum, could be used for monocots or gymnosperms, with a reasonable expectation of success" (Office Action dated January 15, 2003, page 7), the evidence of record does not support this allegation. The Office Action cites Hansen, *et al.*, *Trends in Plant Science* 4:226-231 (1999) (hereinafter "the Hansen reference") for support, but the Hansen reference is not directed to methods of plant transformation that involve electroporation and, in fact, contains only a single sentence that makes reference to electroporation. Rather, the reference is directed to protoplast transformation, biolistics transformation, and agrobacterium-mediated transformation. (See page 228.) Accordingly, the Hansen reference does not constitute evidence that establishes a reasonable basis to doubt the objective truth of the statements contained in the specification ***regarding the claimed subject matter***.

In fact, the Office Action has failed to offer any evidence or reasoning that establishes a basis to doubt the truth or accuracy of the teachings provided in the specification with respect to the claimed methods. The Office Action has merely offered general, conclusory statements as to alleged unpredictability in the art. Accordingly, the Office Action has failed to support its assertions of lack of enablement with acceptable evidence or reasoning that is ***specific*** to the claimed methods, and has therefore failed to meet its burden in establishing lack of enablement.

Applicants respectfully submit that the specification enables those skilled in the art to make and use the full scope of the claimed subject matter without undue experimentation, and accordingly, respectfully request withdrawal of the rejection.

Alleged Anticipation

Claims 1 to 17, 19, 20, 28, and 30 to 33 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,859,327 (hereinafter "the Dev patent"). Applicants respectfully traverse the rejection because the Dev patent fails to teach or suggest every limitation of the claims. For example, the Dev patent fails to teach or suggest ***culturing an explant*** of the plant that is to be transformed ***in nutritive medium*** prior to electroporation. Although the Office Action asserts that the Dev patent teaches culturing an intact explant in nutritive medium prior to electroporation, and cites column 15, line 60 to 66 of the patent in support of the assertion, the patent, in fact, contains no such teaching. (Office Action dated January 15, 2003, page 8). The cited passage of the Dev patent describes transformation of lettuce by growing lettuce seeds on agar to produce cotyledons. The cotyledons were then grown for six days to obtain larger leaf sizes. Circular leaf discs were then cut from the cotyledons and electroporated. The leaf discs were ***not*** cultured with nutritive medium prior to electroporation. Accordingly, the cited passage of the Dev patent fails to teach or suggest culturing an ***explant*** of the lettuce in nutritive medium prior to electroporation.

To the extent that the Office Action considers growth of the cotyledons to obtain larger leaf sizes to be the culturing of an explant, Applicants respectfully disagree. Applicants respectfully submit that the leaf discs that were cut from the cotyldons were the explants that were transformed in the described experiments, and the cotyldons themselves were not transformed. Accordingly, the explants that were used in the transformation experiments were not grown in nutritive medium prior to electroporation. The Dev patent

therefore fails to teach or suggest every limitation of the claims, and Applicants respectfully request withdrawal of the rejection.

Alleged Obviousness

Claims 1 to 20 and 28 to 43 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over the Dev patent in view of prior art identified in the specification. Applicants respectfully traverse the rejection because it appears to be based on the assumption that the Dev patent teaches all the limitations of the claims except the limitations relating to an IPT gene, the CONSTANS gene, a transgene modifying the flowering response, a member of the GATA1 family of transcription factors, zinc-finger containing transcription factors, the GAI gene and genes for gibberellin signaling proteins, SH2-like transcription factors, transcription factors, and transgenes comprising a signal transduction domain. (Office Action dated January 15, 2003, page 9). Because this assumption is incorrect, as noted above, Applicants respectfully request withdrawal of the rejection.

Information Disclosure Statement

Applicants would like to thank the Examiner for returning initialed copies of the 1449 Forms that were submitted in connection with the Information Disclosure Statements filed November 1, 2000 and November 14, 2002. Applicants have not yet received initialed copies of the 1449 Form that was submitted in connection with the Supplemental Information Disclosure Statement filed May 9, 2002, however. Enclosed is an additional copy of the 1449 Form submitted in connection with the Supplemental Information Disclosure Statement filed May 9, 2002 and a copy of the date-stamped postcard indicating that the Supplemental Information Disclosure Statement, 1449 Form, and the four references listed on the 1449

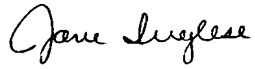
Form were received by the Patent Office on May 16, 2002. Applicants respectfully ask the Examiner to initial the 1449 Form and return it to Applicants, confirming consideration of the listed references.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable Action is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

Respectfully submitted,



Date: **May 29, 2003**

Jane E. Inglese, Ph.D.
Registration No. **48,444**

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims

Claims 1, 7 to 9, and 15 to 18 have been amended as follows.

1. (Amended) A method for transforming a plant with [a] at least one transgene, comprising the steps of:

a. culturing an [intact] explant of [the] a plant in nutritive medium;

b. electroporating the cultured explant and at least one transgene with a pulse length of at least about 50 milliseconds to produce a transformed explant;

wherein the cells of the explant are not subjected to enzymatic digestion or partial enzymatic digestion of their cell walls and the transgene is stably integrated into a chromosome of a cell of the transformed explant.

7. (Amended) The method of claim 1, wherein a [marker gene] nucleic acid encoding a marker is also electroporated in step b.

8. (Amended) The method of claim 6, wherein a [marker gene] nucleic acid encoding a marker that is on a separate DNA molecule than the at least one transgene is also electroporated in step b.

9. (Amended) A method of producing a transgenic plant comprising the steps of:

a. culturing an [intact] explant of a plant in nutritive medium;

b. electroporating the cultured explant and at least one transgene with a pulse length of from about 50 to about 500 milliseconds to produce a transformed explant, wherein the cells of the explant are not subjected to enzymatic digestion or partial enzymatic digestion of their cell walls and the transgene is stably integrated into a chromosome of a cell of the transformed explant; and

c. regenerating the transgenic plant from said transformed explant.

15. (Amended) The method of claim 9, wherein a [marker gene] nucleic acid encoding a marker is also electroporated in step b.

16. (Amended) The method of claim 9, wherein a [marker gene] nucleic acid encoding a marker that is on a separate DNA molecule than the at least one transgene is also electroporated in step b.

17. (Amended) The method of claim 16, wherein the transgenic plant lacks the [marker gene] nucleic acid encoding a marker.

18. (Amended) The method of claim 16, wherein the [marker gene is the IPT gene] nucleic acid encoding a marker encodes isopentenyl transferase.

Claims 21 to 27 and 35 to 43 have been cancelled.